ATTACHMENT 3

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

K012554

JAN 2 9 2002

Official Contact	David J. Vanella Manager, Regulatory Affairs/Product Assurance Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Classification Reference	21 CFR 868.5905
Product Code	BZD – Non-Continuous ventilator
Common/Usual Name	CPAP System
Proprietary Name	Respironics REMstar Auto CPAP System
Predicate Device(s)	Model 7410 Voyager (K974879) Respironics Remstar Plus CPAP System/Remstar Heated Humidifier (K010263) Respironics Virtuoso LX CPAP System (K993433)
Reason for submission	Modified design, additional accessories.

Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate device:

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

Design verification tests were performed on the REMstar Auto CPAP System because of the risk analysis and product requirements. All tests were verified to meet the required acceptance criteria. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate device.

The modified device complies with the applicable standards referenced in the Guidance for FDA Reviewers and Industry "Guidance for the Content of premarket Submissions for Software Contained in Medical Devices", May 1998.

Intended Use

The REMstar Auto CPAP System delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea. This device is intended for use in the home or hospital/institutional environment on adult patients.

Device Description

The REMstar Auto Continuous Positive Airway Pressure (CPAP) System is a microprocessor-controlled, blower-based system that generates positive airway pressures from 4 to 20 cmH_2O. The device is intended for use with a patient circuit that is used to connect the device to the patient interface (mask). The Respironics Model 7410 Voyager has been modified to detect hypopneas and to add an interface to adjust the settings of the Remstar Heated Humidifier. The design implementation of the humidifier and the humidifier interface is the same as the Remstar Plus CPAP System (K010263). The basic functional and performance characteristic of the REMstar Auto CPAP System is unchanged from the predicate device (Model 7410 Voyager K974879).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2002

Mr. David J. Vanella
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668

Re: K012554
Respironics® REMstar Auto CPAP System
Regulation Number: 868.5905
Regulation Name: Non-continuous Ventilator
Regulatory Class: Class II (two)
Product Code: BZD
Dated: January 2, 2002
Received: January 3, 2002

Dear Mr. Vanella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

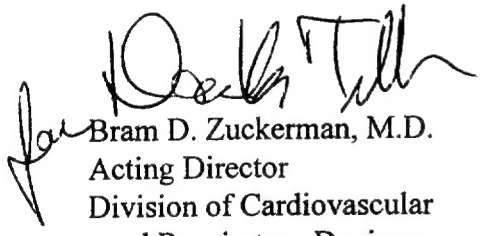
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012554

510(k) Number (if known): K012554

Device Name: Respironics® REMstar Auto CPAP System

Intended Use/Indications for Use

The REMstar Auto CPAP System delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea.

Environment of Use/Patient Population

For use in the home or hospital/institutional environment on adult patients.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012554